

SEP 12 1996



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
ASSISTANT SECRETARY AND COMMISSIONER
OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

#9

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 5,212,303, was filed on July 26, 1996, under 35 U.S.C. § 156. U.S. Patent No. 5,212,303 issued on May 18, 1993 from an application that was filed on September 28, 1992 and which claimed priority to an application filed on April 10, 1986.

The assistance of your Office is requested in confirming that the product identified in the application, DIFFERIN Solution, 0.1%, has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156. However, it is noted that another application for patent term extension for the above-identified patent has been filed based upon the regulatory review period of the product DIFFERIN Topical Gel, 0.1% and that the regulatory review periods of both DIFFERIN Solution, 0.1% and DIFFERIN Topical Gel, 0.1% have also been relied upon for applications for patent term extension for the patents Re. 34,440, 4,717,720 and 5,015,758.

Inquiries regarding this communication should be directed to Karin Tyson at (703) 306-3159.

Hiram A. Bernstein
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Project

cc: Norman H. Stepno
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